



SFDA SAFETY SIGNAL

“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”

26-06-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Vincristine and the Risk of Endocarditis

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Endocarditis** associated with the use of **Vincristine**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Vincristine Sulfate Injection is indicated in acute leukemia. The mechanism of action of vincristine sulfate has been related to the inhibition of microtubule formation in mitotic spindle, resulting in an arrest of dividing cells at the metaphase stage. ^[1] Endocarditis is a rare and potentially fatal infection of the inner lining of the heart (the endocardium). It's most commonly caused by bacteria entering the blood and travelling to the heart. ^[2] The aim of this review is to evaluate the risk of Endocarditis associated with the use of Vincristine and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, Vigibase, with literature screening to retrieve all related information to assess the causality between Endocarditis and Vincristine use. The search conducted on April 2025.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 33 global case-reports while no local case found. The authors used signal detection tool (Vigilyze) to retrieve global cases. ^[3] Authors also applied WHO-UMC causality assessment criteria on all ICSRs (33 cases). ^[4] Among the reported cases, six were assessed as probably or possibly related to Vincristine, 26 cases could not be evaluated due to insufficient information, and one case was deemed unlikely to be related.

Datamining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association. The IC result is (2.1) for this drug/ADR combination which reflects positive statistical association. ^[4]



Conclusion

The weighted cumulative evidence identified from assessed cases and disproportionality analysis are suggestive for causal association between Vincristine and Endocarditis. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sFDA.gov.sa

References:

- 1- [dailymed.nlm.nih.gov](https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=49596de6-ab18-49d1-9e5b-30968fc21c36). (n.d.). DailyMed - VINCRISTINE SULFATE injection, solution. [online] Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=49596de6-ab18-49d1-9e5b-30968fc21c36>.
- 2- NHS (2022). Overview - Endocarditis. [online] NHS. Available at: <https://www.nhs.uk/conditions/endocarditis/>
- 3- Vigilyze.who-umc.org. 2025. [online] Available at: <https://vigilyze.who-umc.org/>
- 4- World Health Organization WHO (2013). WHO-UMC system for standardised case causality assessment. Available at <https://www.who.int/publications/m/item/WHO-causality-assessment>